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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/611,220	07/06/2000	Scott Arouh	DIA 0002P	4817

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EXAMINER	
ALLEN, MARIANNE P	
ART UNIT	PAPER NUMBER
1631	6

DATE MAILED: 11/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/611,220	AROUH ET AL.	
	Examiner	Art Unit	
	Marianne P. Allen	1631	

-- The MAILING DATE of this communication app ars on the cover she t with the correspondence address --

P riod for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 September 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9,10,14 and 15* is/are pending in the application.

4a) Of the above claim(s) *9* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10, 14-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Applicant's arguments filed 9/3/02 have been fully considered but they are not persuasive.

Election/Restrictions

Claims 9-10 and 14-15 are pending. Claim 9 is withdrawn as being directed to a non-elected invention. Claims 14 and 15 have been examined only with respect to their dependence on claim 10 as previously acknowledged by applicant.

Applicant appears to believe that claim 9 is under examination based on the response submitted. It is not.

Information Disclosure Statement

Applicant is again encouraged to file an information disclosure statement.

Specification

There appears to be text missing from pages 61-62 of the specification. The bottom of page 61 is blank and the top of page 62 is blank. The sentences bordering this section are fragments.

Applicant submitted substitute pages that could not be entered as no marked up copy was provided as required.

In addition, although applicant feels no text is missing, the final text on page 61 does not appear to be completed by the initial text on page 62. It does not appear that just an inadvertent page break was made. Clarification is again requested.

Claim Rejections - 35 USC § 112

Claims 10 and 14-15 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to

reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 10 has been amended changing both the preamble and body of the claim. Basis for these amendments in the specification has not been pointed to and no basis is apparent. Applicant is reminded that they are required to point out support for any changes to the claims.

Should this new matter rejection be overcome, these claims would still be subject to the enablement rejection set forth in the prior Office action and summarized below.

Claims 10 and 14-15 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This is an enablement rejection.

This rejection is maintained for reasons of record and as discussed below.

The SBIR/STTR contract document submitted by applicant was dated well after the instant filing date. This document concerns the instant invention and acknowledges on page 5 that a great deal of software and data preparation had to be invented in order to successfully execute the method. Page 30 documents that the biggest hurdle was obtaining the patient data source and that cost prevented the inventors for generating a patient pool designed for the study. Applicant's arguments with respect to Genaissance and Pharsight are not persuasive as the data from these companies would not have been available at the time of the invention to those of ordinary skill in the art and would not

have included all of the information necessary for the method claimed. Applicant's arguments with respect to Golub et al. are not persuasive. First of all, Golub et al. has not been provided. As far as can be determined from page 13, this is only an identification of genes and does not provide patient (particularly drug dosage) information.

Applicant is reminded that the method under examination requires drug treatment dosages and genomic data for the patients. Identity of the drug alone would not be sufficient. It is maintained that the patient information required to train the neural network would not have been well known and readily available at the time of the invention.

It is further noted that the SBIR/STTR contract document investigated a known pathway with known genomic markers and known drugs for treatment. While applicant argues that this is proof of principle, it would have been more difficult to determine such associations for uncharacterized pathways with no known genomic marks and no known treatments. One of ordinary skill in the art would have had to practice undue experimentation to train, validate, and test a neural network for such data. The analysis and judgment required to do this would not have been routine but have required inventive skill beyond the limited guidance provided by the application. The computational complexity of such a situation would be significantly greater than what this document exemplifies. Note that the application itself provides no exemplification at all.

Associations of alleles to responders or non-responders is not analogous to the claimed method for predicting optimal drug dosage and/or drug efficacy for an individual patient. As such, arguments with respect to Arranz et al. is not persuasive. Furthermore,

these were all known receptors with known polymorphisms. The receptors were known to be responsive to the drug (clozapine).

The press release of Exhibit C is not prior art (accompanied by what appears to be a copy of an e-mail commentary concerning it (signed by Scott)) is not probative. The STRENGTH study was not initiated until April 2001, after the instant filing date. Furthermore, this does not address optimal drug dosages.

The letter to the editor in Exhibit D is not prior art and does not demonstrate that patient allele data and drug dosage data would have been readily available to those of ordinary skill in the art to use in other work. This data would have been confidential. Note the discussion of written informed consent. Again, it does not address optimal drug dosages.

Again, Fullerton et al. demonstrates the complexity and the difficulty in linking allele/SNP patterns to disease. (See discussion.) Collin (Human Heredity, 2000) also discusses the challenges of mapping genes for complex traits. The art's inability to do this much raises the burden to applicant to provide guidance in obtaining the necessary information to practice the claimed invention.

Again, Judson et al. (Pharmacogenomics, February 2000) reviews the predictive power of haplotypes in clinical response. This is a new field and the information required by the claimed method is not available. See at least pages 23-24, section 2.7 and 3.0.

Claims 10 and 14-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 14-15 are indefinite for depending upon non-elected claim 9. These claims should be amended to depend only from claim 10, the elected method.

Claim 10 remains confusing in reciting "genomic data, including alleles and/or characteristic SNP patterns" as set forth in the prior Office action. Applicant is reminded that the phrase "including" in several places renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is 703-308-0666. The examiner can normally be reached on Monday-Friday, 7:00 am - 1:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 703-308-4028. The fax phone

numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Marianne P. Allen
Primary Examiner
Art Unit 1631

mpa
November 18, 2002